REMARKS

The Amendments

The amendments are meant only to conform the claims to the election with traverse of claims 1-5. Applicant does not consider this to affect or reflect on the patentability of claims 6-62 in any manner. Claims 6-62 may be pursued separately by Applicant in one or more future related applications.

The Rejections

Claim Rejections - 35 USC § 112

Claim 5 is rejected under 35 USC § 112, second paragraph, for indefiniteness. The phrase "active truncated derivatives thereof" is described as unclear.

Applicant respectfully disagrees. A claim is not indefinite simply because it is broad. *See In re Miller*, 441 F.2d 689, 693, 169 U.S.P.Q. 597, 600 (C.C.P.A. 1971) ("breadth [of a claim] is not to be equated with indefiniteness, as we have said many times"). The M.P.E.P. cautions the examiner that "[i]f the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph." M.P.E.P. § 2173.04 (Rev. 1, Feb. 2000). According to the M.P.E.P., the proper focus for determining definiteness is "whether the claim meets the threshold requirements of clarity and precision." M.P.E.P. § 2173.02 (Rev. 1, Feb. 2000). "The definiteness inquiry focuses on whether those skilled in the art would understand the

scope of the claim." *Union Pacific Resources Company v. Chesapeake Energy Corporation*, 236 F.3d 684, 692, 57 U.S.P.Q.2d 1293, 1297 (Fed. Cir. 2001).

The Office Action concludes that the phrase "active truncated derivatives thereof" is unclear. But there is no basis set forth to explain why this phrase would not be clear and precise to a person of ordinary skill in the art. The complete phrase in the claim is "insulin growth factor and active truncated derivatives thereof." Thus, the phrase "active truncated derivatives thereof" refers only to such derivatives of insulin growth factor. And, just as with other natural agents that operate by interacting with receptor sites, one of ordinary skill in the art would recognize that active truncated derivatives of insulin growth factor may be useful to produce results similar to those achieved using the insulin growth factor itself.

The specific words used in this phrase are clear, ordinary words in the industry. Clearly, in combination with the level of general knowledge and expertise and on the basis of the specification's disclosure and discussion, one of ordinary skill in the art would readily understand what is meant by this phrase, without needing a laundry list of the potential derivatives that would fit this general description. Further, any such laundry list would be practically guaranteed to be incomplete, by the very nature of such derivatives. Accordingly, Applicant respectfully requests that this rejection be reconsidered and withdrawn.

Claim Rejections - 35 USC § 102(a)

Claims 1, 3, and 4 are rejected under 35 USC § 102(a) as being anticipated by Moloney et al. (J. Med. Chem., 7/15/99, Vol. 42, pages 2504-2526). Moloney is said to

disclose compounds 78 and 79, which are embraced by the instant invention, on page 2508.

Applicant respectfully disagrees. To begin with, Moloney does not describe a composition with "an additional neurotrophic factor," such as claimed in claim 4. Accordingly, this rejection should be reconsidered and withdrawn at least with regard to claim 4.

Further, Moloney discloses the two cited compound structures only as intermediates in the middle of an extended set of synthesis reactions, with no suggested or recognized pharmaceutical properties, or use as part of a pharmaceutical composition. Accordingly, Moloney does not enable the instant invention, and should not be considered to anticipate the claimed pharmaceutical compounds. See *Chester v. Miller*, 906 F.2d 1574, 1576 n.2, 15 U.S.P.Q.2d 1333, 1336 n.2 (Fed. Cir. 1990). Accordingly, this rejection should be reconsidered and withdrawn.

Claim Rejections - 35 USC § 102(b)

Claims 1 and 3-5 are rejected under 35 USC § 102(b) as being anticipated by eight separate references -- each is said to disclose products covered by the instant claims.

Applicant respectfully disagrees. Each reference is discussed in turn.

A) Imbach et al., CA 60:2923b, 1964 (CA Reg. No. 97359-06-3)

Imbach is titled "nucleophilic substitution reactions of fluoronitrobenzenes by methylimidazoles." The Office Action does not specify any particular compound alleged to be "embraced by the instant claims." Applicant respectfully requests that this rejection be set forth clearly and with specificity. See *In re Mullin*, 481 F.2d 1333, 1336, 179 U.S.P.Q. 97, 100 (CCPA 1973). Again, Imbach does not seem to suggest any particular pharmaceutical property or usage of any compound. Imbach should not be deemed to enable the claimed pharmaceutical compositions -- especially in claims 3-5 which include a pharmaceutically acceptable carrier. The rejection over this reference should be reconsidered and withdrawn, or set forth with specificity.

B) Wakabayashi et al., JP 52083686 (for instance, Examples 1, 30, etc. on pages 880 and 882, respectively).

The rejection over Wakabayashi does not cite any suggested or recognized pharmaceutical properties, or any use or potential use of the compound structures as part of a pharmaceutical composition. Thus, this rejection should be reconsidered and withdrawn.

C) GB 1,503,244 (for instance, Example 1(A) on page 6)

The rejection over GB 1,503,244 does not cite any suggested or recognized pharmaceutical properties, or any use or potential use of the compound structures as part

of a pharmaceutical composition. Thus, this rejection should be reconsidered and withdrawn.

D) Liao et al., CA 102:6312, 1985 (CA Reg. No. 92763-94-5)

The Office Action does not specify any particular compound alleged to be "embraced by the instant claims." Applicant respectfully requests that this rejection be set forth clearly and with specificity. See *In re Mullin*, 481 F.2d 1333, 1336, 179 U.S.P.Q. 97, 100 (CCPA 1973). Also, Liao does not seem to suggest any particular pharmaceutical property or usage of any compound. Liao should not be deemed to enable the claimed pharmaceutical compositions. The rejection over this reference should be reconsidered and withdrawn, or set forth with specificity.

E) Jamieson, et al., U.S. Pat. 4,230,709 (for instance, Example 8 in column 5)

The rejection over Jamieson does not cite any suggested or recognized pharmaceutical properties, or any use or potential use of the compound structures as part of a pharmaceutical composition. Thus, this rejection should be reconsidered and withdrawn.

F) Takai, et al., U.S. Pat. 4,668,683 (for instance, Example 24 in columns 17-18)

The cited portion of Takai, at Example 24, is not within the instant claims. Example 24 of Takai recites a compound containing a quinazoline structure, which is not within any of the instant claims. In contrast, the instant claims contain a hydantoin or hydantoin

derivative, as defined in the specification, and which is not included in Example 24 of Takai. Accordingly, this rejection should be reconsidered and withdrawn.

G) Lopez Rodriquez et al., WO 96/06846 (for instance, CA reg. no. 178481-97-5)

The Office Action does not specify the portion of Lopez Rodriquez that contains the compound alleged to be "embraced by the instant claims." Applicant respectfully requests that this rejection be set forth with specificity. See *In re Mullin*, 481 F.2d 1333, 1336, 179 U.S.P.Q. 97, 100 (CCPA 1973).

Generally, Lopez Rodriquez appears to relate to compounds containing a phenylpiperazine structure, which is not within claim 1 of the instant application. Also, there is no citation that Lopez Rodriquez suggests any particular pharmaceutical property or usage of any compound. Thus, Lopez Rodriquez should not be deemed to enable the claimed pharmaceutical compositions. Accordingly, this rejection should be reconsidered and withdrawn, or set forth with specificity.

H) Lopez-Rodriquez, J. Med. Chem., 5/23/97, Vol. 40, pages 1648-1656 (for instance, Compound 1a in Table 1 on page 1650)

The cited portion of Lopez-Rodriquez, at Compound 1a, is not within the instant claims. Compound 1a recites a compound containing a phenylpiperazine structure, which is not within claim 1 of the instant application. Also, there is no citation that Lopez Rodriquez suggests any particular pharmaceutical property or usage of any compound.

Thus, Lopez Rodriquez should not be deemed to enable the claimed pharmaceutical compositions. Accordingly, this rejection should be reconsidered and withdrawn.

Claim Rejections - 35 USC § 103

Claims 1-5 are rejected under 35 USC § 103(a) as being unpatentable over Wakabayashi, GB 1,503,244, Jamieson, Takai, and Lopez Rodriquez (WO 96/06846). The Office Action notes that "Applicant claims hydantoin products. Each of Wakabayashi (page 877), GB 1,503,244 (page 2, Formula I), Jamieson (column 1, Formula I), Takai (columns 13-18), and Lopez Rodriquez (pages 1-2) teach hydantoin products which are structurally similar to the instant claimed products.

Applicant respectfully disagrees. First, as discussed above, Takai and Lopez Rodriquez do not relate to hydantoin products of the same general formula as claimed in the instant specification. Second, there is no suggestion in any of the cited art that the claimed compositions have any pharmaceutical properties or use. Thus, these references should not be deemed to make obvious the inventions in claims 3-5, relating to pharmaceutical compositions.

Third, the approximately 10-15 compounds disclosed in the remaining prior art references, in context, provide absolutely no incentive for one of ordinary skill in the art to prepare the claimed compounds. A prima facie case of obviousness requires that the prior art provide some suggestion or incentive to make the claimed substitution. *In re Grabiak*, 769 F.2d 729, 731-32, 226 U.S.P.Q. 870, 872 (Fed. Cir. 1985). The limited number of disclosures even in the cited prior art combined does not teach or suggest applicant's

claimed substitutions. Because the cited prior art also fails to teach the utility of the claimed compounds, there was no incentive in the prior art to arrive at the claimed formulations.

The reliance in the Office Action on *In re Lemin*, 141 U.S.P.Q. 814 (1964) also appears to be misplaced. In *In re Lemin*, the claimed compounds shared a common utility with the prior art compounds. Here, the cited references disclose compounds that are merely structurally similar, with no disclosure of similar properties or utilities.

Applicant respectfully requests that this rejection be reconsidered and withdrawn.

CONCLUSION

Based upon the above remarks, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to enter the amendments, to reconsider and withdraw the rejections of record, and to issue a Notice of Allowance.

Serial No. 09/741,437
23758 (269/299)

The Examiner is welcome to telephone the undersigned attorney directly if warranted, here in Washington, D.C. at (202) 974-6004.

Respectfully submitted,

LYON & LYON LLP

Dated: 13 December 2001

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